BILLING INSTRUCTIONS FOR SYNAGIS
(STARTING WITH RSV SEASON 2007-2008)

A major change in billing instructions for Synagis is necessitated with the implementation of the State's new Pharmacy Benefit Manager's new claim adjudication system.

Attached are the new Synagis Prior-Authorization forms available at State DHMH's website, http://www.dhmh.state.md.us/mma/mpap/forms.htm

The clinical criteria for the approval of payment for Synagis have not changed for the 2007-2008 RSV season.

Effective Oct 15, 2007, providers may bill on-line for Synagis after submitting the Prescriber Statement of Medical Necessity for the drug to the State by fax and after being notified by the State of the approval for payment for Synagis for the fee-for-service Maryland Medical Assistance recipient.

The claim will initially deny on-line. Pharmacy providers are to submit the Synagis Service PA form to the State for an override of all denial codes. A minimum of 3 weight measurements must be documented on the Service PA form for a determination of an estimate of the dosage and number of vials needed for the first injection. A nurse or prescriber's signature is required on the form for all documentation of weight measurements.

The State will enter the prior-authorization on-line for the recipient for the whole RSV season, from Oct 15, 2007 to Mar 31, 2008, based on the initial dosage for the first injection. After entering the appropriate overrides for the numerous exception codes associated with the claim denial at the point-of-sale, the State will notify providers of the clearance of those denial codes for claim resubmission, preferably this year by email, and if not possible, by fax, or by phone calls. This year, the contact persons for verification of the issuance of those Service prior-authorizations will be:

Ron Poole- Phone: 410-767-5949
Andrea Pope- Phone: 410-767-2641
Tuong Nguyen- Phone: 410-767-5701

If the recipient should be moved to an MCO after the initial prior-auth has been issued by the State for the whole RSV season, providers will get a denial on the Synagis claim because of the built-in eligibility system checks which prompt providers to bill the correct insurance plan.

If and when providers need to send more vials due to an increase in body weight, they should fax another Synagis service PA form to the State, documenting the new weight on the form and requesting an adjustment to the original prior-authorization.

Prior-authorization should always be obtained prior to the drug being shipped and not after the fact. The State will not cover shipment of unnecessary vials shipped that do no reflect the dosage prescribed or the documented weight measurements.

For homecare providers who intend to administer Synagis to their patients at the recipients' home and bill the State for the actual number of vials used based on current body weight immediately after the service is rendered, the State will allow post-service payment only if the billing is done within reasonable time, meaning before the next dose is given, and not several months later as this problem has occurred in the past, provided the quantity billed is consistent with the weight measurement history.

Any questions regarding Synagis may be directed to the Clinical Pharmacist Consultant for DHMH at 410-767-5701.

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PRESCRIBER'S STATEMENT OF MEDICAL NECESSITY
Prior-Authorization - Synagis (palivizumab)
Maryland Pharmacy Program- Division of Pharmacy Services
Tel#: 410-767-1455 or 1-800-492-5231- Option 3
Fax form to: 410-333-5398 (**Incomplete forms will be returned**)

Patient Information

Patient location: ____ home; ____ hospital___ Clinic___Office - Check one: ___ 1st RSV season __ 2nd season
List dates of previous injections received at the hospital or MCO clinic: _____
Patient Name:_____
Address: _____
MA ID#:_____
Tel.#: (_____) _____-_____ Weight at birth:_____lb _____kg Date of Birth:_____/____/____
Gestational age:_____wks; Most Current Weight:_____lb _____kg Date weighed:____/____/_____

Prescriber Information

A copy of the patient's hospital discharge summary must accompany this prior-auth request. For Maryland, the typical RSV season runs **from Nov 1 to Mar 31**. Up to **5 doses*** will be approved per RSV season**.** Prior-authorization requests will be handled as early as Oct 15 to allow ample time for billing and shipping. Administration of Synagis is to start **Nov. 1**.
Must meet ONE of the following six criteria**:

- ❑ Infant or child < 2 years old with chronic lung disease* (CLD or bronchopulmonary dysplasia) and on medical treatment for CLD within 6 months of RSV season. Was CLD confirmed by Chest X-Rays? Yes___ No___
  How long was patient on O2 at birth?____days
  Did the child have a need for supplemental O2 beyond the 28th day of life? Yes___ No___
  Did the patient have a history of lung injury at birth? Yes____No____
  Does the patient have persistent respiratory difficulty beyond 28 days of age? Yes_____ No_____
  Has patient been treated for CLD within 6 months of start of RSV season? Yes_____ No_____
  List medical therapy for CLD (O2, bronchodilators, diuretics, etc) within 6 months of RSV season:_____
  Last date of treatment for CLD:_____
- ❑ Born at 28 6/7 weeks gestation or earlier and patient is currently 12 months of age or younger.
- ❑ Born at 29-32 6/7 weeks gestation and patient is currently 6 months of age or younger.
- ❑ Born at 33-35 weeks gestation and patient is currently 6 months of age or younger with **at least 2** additional risk factors (Check qualifying risk factors):
  __ severe neuromuscular disease __ smoking in the home __ school-aged siblings
  __ child care attendance __ congenital abnormalities of the airways
- ❑ Infant or child <2y/o with severe immunodeficiencies (eg. Severe combined immunodeficiency or severe acquired immunodeficiency syndrome) who may benefit form prophylaxis.
- ❑ Infant or child younger then 2 years of age with hemodynamically significant (cyanotic or acyanotic) congenital heart disease (CHD) including the following: _____moderate to severe pulmonary artery hypertension (PAH) or ____congestive heart failure (CHF). List medication for CHF or PAH: _____

Synagis is not considered medically necessary for infants with the following conditions for which he/she **is not** at increased risk from RSV and generally **should not** receive immunoprophylaxis (check proper diagnosis):
□ Hemodynamically **insignificant** heart disease (eg, secundum atrial septal defect, small ventricular septal defect (VSD), pulmonic stenosis, uncomplicated aortic stenosis, mild aorta coarctation and patent ductus arteriosus)
□ Lesions adequately corrected by surgery, unless patient continues to require medication for congestive heart failure □ **Mild** cardiomyopathy not requiring medical therapy
* Per AAP, a total of 5 monthly doses of Synagis will provide over 20 weeks of serum antibody levels which should be protective and cover most of the RSV season even with variation in season onset and end. No need for a 6th dose.
** If not meeting criteria, provide recommendation letter from a neonatal or pediatric pulmonologist.
Name of Pharmacy where prescription will be filled:_____
Tel.#: (_____)-_____- _____ Fax# : (_____) _____ - _____
RX- Synagis (palivizumab) _____mg IM q month – Nurse to fax a history of 3 most recent weight measurements to the State using attached Synagis Service PA form. Current weight:_____kg_____lb ; Date:_____/_____/_____

I certify that this treatment is medically necessary and meets the guidelines of the American Academy of Pediatrics (AAP). Supporting documentation of the patient's diagnoses and weight changes is available for audit in the patient's medical record.
_____, M.D. **Prescriber's Name**:_____
Prescriber's signature Date:_____ Address: _____
Tel# (____) – _____- _____Fax#__ (____) - _____ _____ _____
Specialty: _____
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BILLING INSTRUCTIONS FOR SYNAGIS

Questions concerning billing instructions and prior-authorization for Synagis should be directed to the Division of Pharmacy Services at 410-767-1455 or 1-800-492-5231- Option 3 (out-of-area only).

Billing of Synagis by Retail Pharmacy or IV Infusion Pharmacy Providers

Synagis may be dispensed and billed on-line between Oct. 15 and Mar 31. After receiving notification of approval of payment for Synagis for the entire RSV season, and after verifying that the recipient is enrolled in fee-for -service MA, pharmacy providers may bill on-line as follows before shipping the drug:

1. Bill the non-compound code (0 or 1). Bill days supply= 28 (Prior-auth will be based on 28 days supply).
2. Bill the NDC and corresponding quantity (unit=ml) dispensed. For a dose of 132mg, bill quantity of "1"for '1 ml" for the 100mg/1ml package size liquid vial (NDC# 60574-4113-01) and "0.5" for 0.5ml of the 50mg/ml liquid vial (NDC# 60574-4114-01). Due to the high cost of the drug, the Program will allow the number of vials listed below based on 15mg (+/-5%)/kg. The dosing is based on the patient's estimated body weight at the time of injection.

Calculated Dose Per Month based on 15mg/Kg	Number of vials (powder) required
From 0 to 52mg	1 x 50mg vial (Bill qty = 0.5 for 0.5ml of the 50mg/0.5ml vial NDC)
From 53 to to 105mg	1 x 100mg vial (Bill qty =1 for 1ml of the 100mg/ml vial NDC)
From 106mg to 157mg	1 x 100mg vial (Bill qty= 1 for 1 ml for the 100mg vial NDC) + 1x 50mg vial (qty =0.5 for 0.5ml for the 50mg/ml vial NDC)
From 158mg to 210mg	2 x 100mg vials (Bill qty = 2 for 2ml of the 100mg/ml vial NDC)
From 211mg to 262mg	2 x 100mg vials (Bill qty = 2 for 2ml of the 100mg/ml vial NDC) + 1 x 50mg vial (Bill qty= 0.5 for 0.5ml of the 50mg/ml vial NDC)
From 263mg to 315mg	3 x 100 mg vials (Bill qty = 3 for 3ml of the 100mg/ml vial NDC)

3. When submitted on-line, claim will deny with multiple exception codes requiring service prior-authorization from the State. Providers are to fax to the Program the Synagis Service Prior-Auth form that must be completed and signed by the nurse or prescriber. A history of at least 3 most recent weight measurements is required for processing the Synagis service PA request.
4. Based on the estimated weight at time of scheduled first Synagis injection, the Program will override the appropriate exception or denial codes to allow claims to go through for the whole RSV season for the number of vials needed. If the patient requires additional vials for subsequent months, providers are to call the State for an adjustment to the prior-authorized number of vials and fax a new Service PA form to the State for each request. Programs should not overstate the weight for the initial injection since subsequent adjustment of the initial prior-authorization can be made anytime.
5. Any vials that are returned unused, sealed or unopen must be credited back to the Program as it is expected that the vials have been properly stored and handled by professionals. Providers only need to reverse the claim(s) from the system to negate any payment previously made by the Program and rebill the correct number of vials that are actually used. This can be done anytime within 9 months of the date of service.

Billing of Synagis by Prescribers

If the prescriber elects to purchase Synagis directly from the wholesaler, he/she must bill the drug under Physician Services, following current billing instructions on how to include an NDC code for Synagis as well as the proper HCPC code (J3490) on the CMS-1500 claim form. The prescriber is responsible for arranging for the pick-up and/or delivery of the product to ensure that it is stored in the refrigerator and handled properly. Whether the drug is billed under Pharmacy Services or Physician Services, any ordered medication for Maryland Medicaid patients that is received by the medical office but unused and unopen must be returned to the pharmacy and credit must be issued to the Program.
The administration charge for Synagis is included in the office visit and therefore is not a separate billable service. Please contact Physicians Services at 410-767-1750 for any other related questions.

Coverage of Synagis for Medical Assistance Recipients Enrolled under Managed Care

Providers must verify recipient eligibility before requesting Synagis from the State. If the recipient is enrolled in HealthChoice (under managed care), they must contact the specific MCO directly to request prior-authorization for payment of Synagis.
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SYNAGIS SERVICE PRIOR-AUTHORIZATION

Maryland Medical Assistance

410-767-1455 or 1-800-492-5231-Option 3

Fax to: 410-333-5398 (Incomplete forms will be returned)

Recipient and Insurance Information

Recipient Name: _____ MA #: _____ MCO patient? □ Yes □ No

Today's date:_____Date of Service (or date shipped):_____

Date of scheduled drug injection: _____ Location: □ Office □ Residence □ Hospital/Clinic

Once prior-authorization (PA) has been issued for the **requested specific date of service, the approved quantity and the approved days supply**, providers must resubmit the claim using these **exact same** data elements. Changing any of these data elements will result in claim not going through. Do not use different dates when referring to the same shipment (i.e when date of service is different from date shipped- Be consistent by using one date for billing purpose).

Third Party Liability: List other insurance: _____

Note: Maryland Medicaid is always the payer of last resort. List units dispensed and payment made by other insurance for coordination of benefits:

NDC 60574-4114-01(50mg/0.5ml vial)-Quantity billed=_____Other insurance paid$_____

NDC 60574-4113-01(100mg/1ml vial)- Quantity billed=_____Other insurance paid:$_____

Refer to Worksheet below for instructions on determination of number of Synagis vials to ship. Bill fractional units if vials are to be shared with other Maryland Medicaid patients.

Required Documentation of Patient's Weight History

Documentation of a minimum of 3 prior actual weight measurements is required for the processing of each Service PA.

Date of Weight Measurement	Actual Weight As Documented in Medical Record
	□ lb. □ kg
	□ lb. □ kg.
	□ lb. □ kg.
	□ lb. □ kg.
	□ lb. □ kg.
	□ lb. □ kg.

_____, Date_____

Signature of Medical Staff (CNP, or RN, or MD) Phone:_____Fax:___ _____

I certify to the validity of the patient's weight data as submitted. Supporting medical documentation is available in the patient's medical record for the weights based on which the doses were calculated.

Please print Name:_____Title: □ NCP - □ MD - □ RN

This Service Prior-Auth Request will not be processed if not signed by a medical staff.

Pharmacy where Rx will be filled:_____Phone: _____

Contact Person: _____Fax: _____email:_____

FOR INTERNAL USE

Approved from:_____to _____ **Reviewer's Initials: _____**

Bill quantity of 0.5 for each 50mg vial and quantity of 1 for each 100mg vial

Billing Time frame: Oct 15 – Apr 13 - Administration Time Frame: Nov 1–Mar 31

(with possible extension to Apr 15 depending on reported culture data at the end of Mar)

100mg vials-NDC 60574-4113-01 (100mg/ml) = Quantity approved: _____Days Supply_____

50mg vials-NDC=60574-4114-01 (50mg/0.5ml) = Quantity approved: _____Days Supply_____

EC: □ 4701, 4145, 4713 = PA required- to be overridden for all situations-

EC: □ 4176 = Cost exceeds $2,500 with more than 1 vial (either 50mg or 100mg)

□ 4194 = Therapeutic duplication when both 50mg and 100mg vials are billed

□ 4656 = Max quantity exceeds (> 1 vial= OK to override **only** for the 100mg vials

□ 4452 = Time between Date Written and Date of Service exceeds plan limits

□ 4134 and 4135 for long-term PA (>30 days) in anticipation of stable body weight.

WORKSHEET FOR USE
IN DETERMINING THE NUMBER OF VIALS TO BILL

A= Recipient's actual weight used for calculating last month's injection:
_____lbs or _____kgs- Weight measured on :_____/_____/_____

B= Calculated average weight gain *per month:_____kg/month (Difference between the last 2 consecutive weight measurement x 28 days : days intervals between the 2 measurements)
Weight measurement # 1: _____lbs or _____kgs taken on _____
Weight measurement # 2: _____lbs or _____kgs taken on _____
* Average weight gain= Weight measurement #2 minus Weight measurement #1, assuming Patient did not lose weight. Ex: If the days interval between the 2 measurements is 19 days between the 2 weight measurements, then prorate per 28 days)=
Weight measurement #2 – Weight measurement #1 x 28 days : 19 days

C= Estimated weight to be used in dosing this month's injection: Add the average weight gain per month (B) to the previous month's weight measurement (A): C = A + B

Estimated dose needed for this month's injection: 15mg X estimated weight C (kg)
Number of vials to bill and ship: Refer to the Synagis Dose Chart.

NOTE

If the Synagis dose falls within a certain range, it will be rounded up or down to the closest vial size within +/- 5%. This will reduce cost, wastage of medication, while still providing effective coverage against RSV.

The American Association of Pediatrics (AAP) (1, 2) recommends 5 monthly doses of Synagis which will provide protection during RSV season, even with variations in the onset and end of the season. Meissner et al *(2004) also cite evidence supporting the AAP position that no more than 5 doses are needed because this recommendation was derived from the design of clinical trials with Synagis. In the Impact-RSV trial and the trial involving children with hemodynamically significant congenital disease, 5 monthly doses of Synagis resulted in serum concentrations 30 microgram/ml for over 20 weeks in almost all subjects. A serum concentration of 30 microgram/ml is the proposed serologic correlate of protection in which this concentration results in a decrease in pulmonary RSV replication by more than 100-fold. One month after the fourth monthly dose of Synagis, the mean serum trough concentration was 72 microgram/ml among subjects in the Impact-RSV trial and 90 microgram/ml in subjects in the cardiac trial, indicating that the trough serum level more than 30 days after the 5th dose will be greater than 30 microgram/ml for most children. Thus, for most infants, 5 monthtly doses will provide substantially over 5 months of serum antibody levels. This should be protective and cover most of the RSV season even with variation in season onset and end.

Service Prior-auth for Synagis will be granted within 24 hours between Oct 15 throughout Mar 31 (with possible extension to April 13 depending of the RSV culture data reported at the end of March) of the RSV season. The prescriber and/or nursing staff must complete and fax the Service PA request form to their pharmacy Program each month to request a shipment of Synagis once the patient has been approved for Synagis for the entire RSV season. The State will notify the pharmacy to submit the claim on-line n override for the denied claim. and upon receiving a call or a fax from the State, providers should resubmit the claim which initially denied, after the override has been issued. If the PA request is placed before noon time, it will be processed before the end of the business day. If the request is made after noon time, it will be handled the following day. A one week time frame will be allowed for providers to resubmit the claim on-line to allow ample time for billing and shipping. A quantity restriction will be entered for the specific number of vials approved based on the estimated body weight. This service PA will be needed **each month** for each recipient.

REFERENCES

(1) American Academy of Pediatrics (AAP), Revised indications for the use of palivizumab and respiratory syncytial virus immune globulin intravenous for the preventin of respiratory syncytial virus infections. Pediatrics. 2003;112(6 Pt1);1442-1446. Available at http://aappolicy.aappublications.org/cgi/content/full/pediatrics;112/6/1442. Accessed Sept 14, 06
(2) Meissner JC, Anderson LJ, Pickering LK. Annual variation in respiratory syncytial virus season and decisions regarding immunoprophylaxis with palivizumab. Pediatrics. 2004;104(4):1082-1084.